

40. The method of claim 35, wherein said galactoside comprises lactose, hyaluronic acid, pectin and derivatives thereof.

41. (See Above)

REMARKS

The Claimed Invention: Respectfully, the claimed invention is not a composition of matter, a generic drug class, or a species of drug, but instead a process. In particular, the process is widely applicable for effecting neuraxial delivery of different 2-amine and 2-amide drugs, in this case, drugs that can be chemically bonded to form the reaction product of Formula I and of the dependent claims therefrom. As a process, not a composition of matter, the claimed invention is afforded examination as a process comprising a series of steps. The meaning of "independent" and "distinct" under 35 U.S.C. § 121 must, therefore, relate to the "steps" of the process, not to species of drugs suitable for use in the process. Since the instant process is a single claim comprising but a single step of forming a chemical bond, it is difficult to see how it can support separate patents as required (MPEP 803), or how the single step can be viewed as "independent" or "distinct" (MPEP 806.04-806.04(i); MPEP 806.05-806.05(i)). Obviously, processes can be used with more than one starting raw material, so Applicant has defined with particularity the starting material, i.e., drug A-B-D, the reactant, i.e., E, and the reaction product, i.e., A-B-D-E.

The claimed process step for improving neuraxial drug delivery (claim 41) involves chemically bonding a 2-amine or 2-amide drug (i.e., the instant A-B-D moiety) to a simple sugar or an oligosaccharide (i.e., the E moiety) to form the reaction product of Formula I (i.e., A-B-D-E). The 2-amine and 2-amide drugs which may be so-coupled are defined with particularity by identifying that the B-moiety comprises one to six carbon atoms, i.e., in advance of the N-group amide or amine (i.e., the D moiety). The nature of the A moiety is defined with particularity as cyclic, heterocyclic or aromatic.

Contrary to the assertions of the Examiner, Applicant does not believe the art of neuraxial drug delivery involving chemical bonding of simple sugars and oligosaccharides to drugs requires an unduly burdensome search. For example, a keyword search conducted by Applicant's agent at the US PTO Patent and Full Text Image Database on March 9, 2002 for "All Years" and "2-amine" in

"Class 514" identified 59 patents; for "2-amide" 8 patents; for "neuraxial" 8 patents; for "amide and saccharide" 437 patents; for "amine and saccharide" 589 patents; for "amide and sugar and neural" 205 patents; and, for "amine and sugar and neural" 205 patents. Structure-based searching for the reaction product of Formula I would be expected to yield significantly fewer hits.

MPEP 803.01 directs as follows: namely,

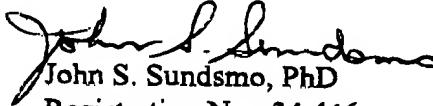
"IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION." (capitalization original)

Amendment of the Claims: Applicant in attempting to comply with the requirements of the Office without unduly limiting the scope of the claimed process, has amended claims 4, 5 and 10 to depend from claim 41, thereby further identify with particularity the nature of the Formula I reaction product. Support for the amendments may be found in the original specification and claims (as filed).

#### CONCLUDING REMARKS

Removal of the restriction requirement and identification of species to be elected are respectfully requested. If any issues remain which can be expeditiously addressed in teleconference, the Examiner is urged to contact Applicant's agent at 760-806-3385.

Respectfully submitted By:

  
John S. Sundsmo, PhD  
Registration No.: 34,446